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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/450,511	11/30/1999	KAORU ARAI	P18214	7711

7055 7590 05/13/2002

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EXAMINER

MAYES, MELVIN C

ART UNIT	PAPER NUMBER
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1734

15

DATE MAILED: 05/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

MF-XS

Office Action Summary

Application No.

09/450,511

Applicant(s)

ARAI ET AL.

Examiner

Melvin C. Mayes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Continued Prosecution Application

(1)

The request filed on April 26, 2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/450,511 is acceptable and a CPA has been established. An action on the CPA follows.

Claim Rejections - 35 USC § 103

(2)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

(3)

Claims 1-9 and 11-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. in view of Ogawa et al., Saita et al. 5,128,169, Shimp et al. and "Modern Ceramic Engineering."

Kim et al. discloses a method of making a ceramic vertebrae prosthesis comprising: providing a dried dense material to correspond to the center portion, providing a dried porous material to correspond to the circumferential portion; adhering the dried dense material to the dried porous material by an apatite slurry; and heating the assembly. The ceramic can be calcium phosphate of Ca/P ratio of 1.0 to 2.0 such as hydroxyapatite and the porous portion is made to have a porosity of 20-55%. Kim et al. disclose heating hydroxyapatite at 1000-1200°C to obtain a final product. Kim et al. disclose that hydroxyapatite slurry can be prepared by a wet composition process using a phosphate salt and calcium salt but does not specifically disclose that the apatite slurry used to adhere the dried materials is synthesized by merely adding a phosphoric compound to a calcium compound slurry (col. 4, lines 18-38, 50-52, col. 5, lines 1-6 and 13-26).

Ogawa et al. teach that hydroxyapatite can be synthesized by various known methods including a wet method in which phosphoric acid or a water-soluble phosphate salt is reacted with a water-soluble calcium compound in an aqueous solution and a dry method in which phosphoric acid compound is reacted with a calcium compound under high temperatures. Ogawa et al. teach making a hydroxyapatite slurry by dropwise adding a phosphoric acid solution to a calcium hydroxide slurry (col. 3, lines 31-52, col. 6, lines 32-40).

Saita et al. teach that for forming a hydroxyapatite coating onto a substrate, hydroxyapatite prepared by a conventional method, such as wet process or dry process, and teaches that the wet process is preferable because a product having fine particle size can easily be obtained and the product of the wet process is preferably used without drying after filtering and washing with water because undesirable production of agglomerates is inhibited. Saita et al. further teach that the particle size of the primary flocculated particles of hydroxyapatite prepared by the wet process is 0.1 to 1 μm when measured by a sedimentation method (col. 2, lines 35-45).

Shimp et al. teach that binders may interfere with the sintering process of hydroxyapatite, even if organic binders which leave no mineral residue upon firing are used (col. 1, lines 40-43).

Modern Ceramic Engineering teaches that sintering of ceramic comprises stages including an initial stage of particle rearrangement and neck formation at the contact point between particles, an intermediate stage of neck growth and grain growth in which a particle begins to grow while the adjacent particle is consumed, and a final stage of much grain growth with porosity elimination (pgs. 520-522).

It would have been obvious to one of ordinary skill in the art to have adhered the dried dense material and dried porous material of hydroxyapatite by an apatite (hydroxyapatite) slurry prior to heating (sintering) in the method of Kim et al. using a slurry prepared by adding a phosphoric compound to a calcium compound slurry, as Ogawa et al. teach that the wet method (in which phosphoric acid or a water-soluble phosphate salt is reacted with a water-soluble calcium compound in an aqueous solution) and the dry method are known methods of making a hydroxyapatite slurry, and Saita et al. teach that for forming a hydroxyapatite coating onto a

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substrate, hydroxyapatite prepared by a wet process is preferable because a product having fine particle size can easily be obtained. Using a slurry or hydroxyapatite particles prepared by a wet process for coating one or both of the dried materials for adhering the materials would have been obvious to one of ordinary skill in the art as preferable for easily providing fine particle size needed for providing a coating, as taught by Saita et al. Using a hydroxyapatite slurry prepared by the wet method would have been obvious to one of ordinary skill in the art because preparing hydroxyapatite slurry by the wet method is well known in the art, as taught by Kim et al., Ogawa et al., and Saita et al.

Using a hydroxyapatite slurry prepared without drying the hydroxyapatite after forming by the wet process, and thus synthesized by merely adding a phosphoric compound to a calcium compound slurry as claimed in Claim 1, would have been obvious to one of ordinary skill in the art as Saita et al. to inhibit the undesirable production of agglomerates. Further, using a hydroxyapatite slurry prepared in the absence of organic components, as claimed in Claim 19, such as organic binder, for coating one or both of the dried materials for adhering the materials would have been obvious to one of ordinary skill in the art, as taught by Shimp et al. to prevent interference with the sintering process of hydroxyapatite.

By heating at 1000-1200°C to obtain a final product, as disclosed by Kim et al., the particles of the slurry fuse and grow during the sintering of the dried dense material and dried porous material, as Modern Ceramic Engineering teaches that sintering of ceramic comprises stages including an initial stage of particle rearrangement and neck formation at the contact point between particles, an intermediate stage of neck growth (i.e. fusing of particles) and grain

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growth, in which a particle begins to grow while the adjacent particle is consumed, and a final stage of much grain growth with porosity elimination.

It would have been obvious to one of ordinary skill in the art to have prepared the slurry to have primary particles of average grain size in the range of 0.1 to 1 μm , and thus including the range of 0.05 to 0.5 μm as claimed in Claim 10, as Saita et al. teach that the particle size of the primary flocculated particles of hydroxyapatite prepared by the wet process is 0.1 to 1 μm when measured by a sedimentation method.

In the event any differences can be shown for the product of the product-by-process claims 17 and 18, as opposed to the product taught by the combination of Kim et al., Ogawa et al., Saita et al., Shimp et al. and "Modern Ceramic Engineering," such differences would have been obvious to one of ordinary skill in the art as a routine modification of the product in the absence of a showing of unexpected results; see also *In re Thorpe*, 227 USPQ 964 (CAFC 1985).

When the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or 103 of the statute is appropriate. As a practical matter, the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith. A lesser burden of proof is required to make out a case of prima facie obviousness for product-by-process claims because of their particular nature than when a product is claimed in the conventional fashion. *In re Brown*, 59 CCPA 1063, 173 USPQ 685 (1972); *In re Fessmann*, 180 USPQ 324 (CCPA 1974).

(4)

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 1 above, and further in view of JP 2-225382.

JP '382 teaches that apatite of average particle size of 0.1 to 15 microns is suitable for applying between apatite products for bonding the products. JP '382 also teaches that the apatite is provided such that it is 5 to 40 wt% of an aqueous solution used for a bonding material (Abstract).

It would have been obvious to one of ordinary skill in the art to have modified the method of the references as combined by providing the amount of apatite in the bonding slurry in an amount in the range of 5 to 40wt%, and thus encompassing the range of 0.1 to 20vol% as claimed in Claim 9, as taught by JP '382 as the amount of apatite in an aqueous solution for a bonding material.

It would have been obvious to one of ordinary skill in the art to have modified the method of the references as combined by providing particles of average grain size in the range of 0.1 to 15 microns in the slurry, and thus 0.05 to 0.5 microns as claimed in Claim 10, as taught by JP '382 as the average particle size of apatite suitable for applying between apatite products for bonding the products.

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Conclusion

(5)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melvin C. Mayes whose telephone number is 703-308-1977. The examiner can normally be reached on Mon-Fri 7:30 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Crispino can be reached on 703-308-3853. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.


Melvin C. Mayes
Primary Examiner
Art Unit 1734

MCM
May 10, 2002